DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 19-034/S-008

Abbott Laboratories
100 Abbott Park Road D
Abbott Park, IL 60064

Attention: David Ross, Pharm. D., MBA
Associate Director, Regulatory Affairs

Dear Dr. Ross:

Please refer to your supplemental new drug application dated March 23, 2000, received March 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dilaudid-HP (hydromorphone hydrochloride, USP) Injection.

We acknowledge receipt of your submissions dated July 12, October 3, and November 9, 2000, and May 3, 2001.

This supplemental new drug application provides for the following changes:

1. Deletion of the statement: "WARNING: May be habit forming."

2. Addition of a safety statement that provides information relating to reports of seizures and myoclonus in severely compromised patients administered high doses of parenteral hydromorphone.

3. Addition of a "Geriatric Use" subsection.

4. Addition of a caution statement for the vial stopper packaging, which contains rubber.

5. Revision of the storage statement.

6. Addition of the "Rx only' symbol.

7. Change of the corporate address of the manufacturer.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 23, 2000), and include the agreed upon labeling for the Geriatric Use subsection as amended by your submission dated May 3, 2001.

Submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-891/S-004, 19-892/S-004." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Cynthia McCormick

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